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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,094	01/03/2001	Mark S. Humayun	55534 (71699)	4130

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,094	HUMAYUN ET AL.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21-35 and 39-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *39-57* is/are allowed.

6)☒ Claim(s) *1-19,21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,8,12,16 and 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Drasner et al (USPN 5,234,406). Drasner discloses a flexible cannula (12) mounted in a second cannula (14). See figure 1. The two cannulas form an infusion fluid path. See 1:50+. Drasner also teaches making the cannulas from polyimide (see 3:14 and 4:6). The second cannula diameter is larger than the first flexible cannula diameter. See figure 1. The proximal end (60) of the second cannula is configured for attachment to a syringe. See 4:59.

Regarding the intended use in the claims (clms 1-4 and 25-33), applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The cannula system of Drasner is capable of performing the intended use of the claims since the prior art cannula meets the structural limitations of the claims, i.e. two cannulas forming an infusion fluid path.

Claims 1-7,12,14-19, and 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by DeCamp et al (USPN 5,792,099). DeCamp discloses a cannula (40) mounted in a second

cannula (36). The cannula and the second cannula form an infusion fluid path. See figure 1. Regarding the flexibility of the cannula, all materials have some inherent flexibility to some degree. Regarding the functional language of insertion into a retinal vein, since the cannula of the prior art has the same gauge as the instant invention, thereby being structurally the same, it is therefore capable of also being inserted into the retinal vein. The cannula (40) itself does not have an external holding device for any amount of time during use.

Claims 1-7,12,14-16,19,21,23-33 rejected under 35 U.S.C. 102(b) as being anticipated by Grinblat et al (USPN 5,545,153). Grinblat discloses illumination and infusion system for retinal surgery that includes a flexible cannula (19) mounted in a second cannula (29). Regarding the flexibility of the cannula, all materials have some inherent flexibility to some degree. Regarding the functional language of insertion into a retinal vein, since the cannula of the prior art has about the same gauge as the instant invention, thereby being structurally similar, it is therefore capable of also being inserted into the retinal vein albeit possibly of an animal that has larger eyes and retinal veins.

Claims 1-4, 12-16 and 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Le et al (US Pat# 6,355,027).

Le discloses a flexible microcatheter system having a flexible cannula (16) with a proximal end and a distal end. The system also has a second cannula (14) having a larger diameter than the flexible cannula and is less flexible (1:46-49). The second cannula has a proximal end and a distal end and a portion of the flexible cannula is housed within the distal end

of the second cannula (see figures 1-3). The second cannula forms a fluid tight seal and mounted about the flexible cannula (see figure 3; the mounting of cannula 14 and 16 within proximal connector 12 must be fluid tight between all three components in order to prevent leaking). The proximal end of the second cannula is sized for attachment (connector 12) to the tip of a syringe.

Regarding the function language in claims 1-4, 16, 25-33 that generally provide for the functioning of the microcatheter or cannula as a hands free injection system. The examiner reminds applicant that function language in device claims is given little patentable weight. As long as the prior art device meets the structural limitations of the claims and is capable of performing the claimed function then the prior art reads on the claims.

In the claims above, the instant invention is a device that injects into the retinal vein of the eye for periods of time from at least 5 min to 2 hours using no support systems to hold the device in position and provides an infusion flow rate of 0.2 cc/min through the proximal end of the second cannula. The prior art is capable of performing this function due to the fact that it is a microcatheter for use in small and tortuous vascular paths and is made from flexible materials.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeCamp. DeCamp meets the claim limitations as described above but fails to include the cannula being made from polyimide.

At the time of the invention it would have been obvious to make the cannula from a material such as polyimide since the catheter is disclosed as having flexible properties and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The motivation for using a medical grade plastic such as polyimide would have been in order to reduce the incidence of allergic reaction of the skin to contact with non-medical grade plastic materials.

Claims 8-11 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le (clms 8-11 and 17-18) and Drasner (clms 9-11 and 17-18), independently. Le meets the claim limitations as described above but fails to include the cannula being made from polyimide and having the flexible cannula and second cannula dimensions of claims 9-11 and 17-18. Drasner fails to include the cannula being made from polyimide and having the flexible cannula and second cannula dimensions of claims 9-11 and 17-18.

At the time of the invention it would have been obvious to make the cannula of Le from a material such as polyimide since the catheter is disclosed as having flexible properties and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The motivation for using a medical grade plastic such as polyimide would have been in order to reduce the incidence of allergic reaction of the skin to contact with non-medical grade plastic materials.

Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 19,21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Applicant's own disclosure. Le meets the claim limitations as described above but fails to include the inner plug.

While Le fails to disclose a modified microcannula system having a silicone plug with a central aperture applicant's own disclosure renders this claim limitation obvious. Page 10 of the instant application states that "microcannula are well known" and "the general features...may be in accordance with conventional catheters". Furthermore, silicone plugs with central apertures (otherwise known in the art as hemostatic valves) are well known in the cannula art and used for maintaining bodily fluids within the body when a larger cannula punctures the body and another instrument is inserted through the larger cannula.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Castora (US Pat# 5947296) or Drasner in view of Castora. Le meets the claim limitations as described above but fails to include a kit including one or more of the catheters packed in sterile conditions.

Castora discloses a catheter kit with multiple catheters packaged in one kit. See figures.

At the time of the invention, it would have been obvious to package the catheter of Le or Drasner as per the organization of Castora since packaging catheters is well known and considered obvious in the art if the catheter is planned for human use.

Allowable Subject Matter

Claims 39-57 are allowed.

Response to Arguments

Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive.

In response to applicant's argument that the Drasner reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the microcatheter system must be sized such that the portion of the device inserted into the retinal vein is no greater than 100 μm/0.1mm) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the DeCamp reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the size of the flexible cannula) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the Grinblast reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the size of the instant invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the Lee reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the size and length of the instant invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams
July 21, 2005

CATHERINE S. WILLIAMS
PRIMARY EXAMINER